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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,276	04/15/2000	GLENN F. SPAULDING	010-US-002	9303

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

19

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,276

Applicant(s)

SPAULDING, GLENN F.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 10-31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10-31, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 2/3/03 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/552,276 is acceptable and a CPA has been established. An action on the CPA follows.

Amendment Entry

2. Applicant's amendment and response filed 2/3/03 in Paper No. 15, is acknowledged and has been entered. Claims 1, 10, 19, 23 and 26 have been amended. Currently, claims 1-4, 10-31, and 33-34 are pending and are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 10-31, and 33-34 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4, is vague and indefinite in reciting, "a light source adapted to illuminate" because it is unclear how the light source has been modified, i.e. adapted, so

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as to be able to illuminate. If Applicant intends that there is no adaptation or modification made to the light source so as to function differentially from any other light source, in illuminating the transparent cylinder, then Applicant should recite, "a light source that illuminates ..." or "a light source for illuminating ...".

Claim 1, line 6 is vague and indefinite in reciting, "a detector adapted to detect" because it is unclear how the detector has been modified, i.e. adapted, so as to be able to detect. If Applicant intends that there is no adaptation or modification made to the detector so as to function differentially from any other cytometer detector, in detecting a light signal, then Applicant should recite, "a detector that detects ..." or "a detector for detecting ...".

Claim 1 stands vague and indefinite in reciting, "cytometric characteristic of a sample" because it is unclear what is encompassed by such a recitation. It is specifically unclear what the determining means in claim 1 intends to determine based on the light signal, i.e. optical density of the resulting spun sample, etc.

Same analogous comments and problems in claim 1 apply to claim 2 in reciting, "a bar code label adapted to be interrogated".

Claim 3 is indefinite in relation to claims 1 and 4, because it is unclear what structural and functional cooperative relationship exists between the "calibration standards" and the "photoactivated crosslinker" which are both affixed on the inner wall of the transparent cylinder. It appears that the "photoactivated crosslinker" is affixed to the inner wall of the transparent cylinder to sort cells; however, it remains unclear what comprises the calibration standards and how it structurally relates to the claimed

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apparatus so as to perform its function as a calibration standard since it does not appear to assist in sorting cells as in the photoactivated linker.

Same analogous comments and problems in claim 1 apply to claim 10 in reciting, "a rotating means adapted to rotate".

Same analogous comments and problems in claim 1 apply to claim 10 in reciting, "a light source adapted to illuminate".

Same analogous comments and problems in claim 1 apply to claim 11 in reciting, "a rotating means further adapted to sequentially rotate". See also claims 12 and 13.

Same analogous comments and problems in claim 1 apply to claim 13 in reciting, "a cap adapted to seal the open end".

Same analogous comments and problems in claim 1 apply to claim 23 in reciting, "a light emitting diode is adapted to emit".

Claim 25, line 4 has improper antecedent basis problem in reciting, "an analog to digital converter", second occurrence in the claim.

Same analogous comments and problems in claim 1 apply to claim 26 in reciting, "light source adapted to illuminate".

Same analogous comments and problems in claim 1 apply to claim 27 in reciting, "light sources are adapted to emit".

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 12 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record.

In this case, the specification does not provide literal or descriptive support for the following parameter requirement, "rotating means is adapted to rotate the transparent cylinder between approximately 50-3000 revolutions per minute". Furthermore, none of the originally filed claims recited any of these limitations in question. Recitation of claim limitations lacking literal and descriptive support in the specification or originally filed claims constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3-4, 10-18, 22, 24-31, and 33-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) in view of Walters (US 6,135,940) for reason of record.

Cottingham discloses an apparatus for mounting a plurality of disposable transparent cylinders (test units) in which flow of sample and reagent liquids can be controlled by centrifugal force applied by relatively simple rotating apparatus. The transparent cylinder comprises a sample chamber having an open end (sample port), a closed end, a guide member having a passage that extends from one end to the other, and a cap (closure or adhesive seal) for sealing the open end of the chamber. The cylinder has immobilized thereto, a reagent having a detectable element disposed in a passage (liquid flow path) for contacting with a biological sample (see column 3, lines 4-32). Specifically, the cylinder is transparent or translucent having a top film with a small opening. The cylinder has a thicker bottom portion and an adhesive seal for closure of the sample port. A passage or channel or series of channels interconnect wells within the cylinder (see column 7, line 42 to column 8, line 8). The cylinder also includes immobilized controls and standards within its inner surface in the form of dried spots (see column 9, lines 31-39). The apparatus comprises a rotating means (circular rotor) for holding and rotating the cylinders about an axis (see column 4). Above the rotor are light sources and optical detectors for illumination and detection of optical responses by the immobilized detectable reagents confined within the cylinder. Light sources include laser diode, photomultiplier tube, CCD, and further comprise diffraction grating (interference filters), lenses, shutters, etc (see column 7, lines 7-35). The transparent cylinder includes organic photoreceptor materials which may be chromogenic, fluorescent, luminescent, or radioactive depending on the substrate used (see column 14, line 64 to column 15, line 16). Lastly, the apparatus includes a processing means

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for operation of the mechanical assembly and for processing signal detected (see column 15, lines 58 to column 16, line 24).

Cottingham et al. differ from the instant invention in failing to disclose rotating the transparent cylinder along a longitudinal axis of the transparent cylinder.

Walters discloses a centrifuge apparatus adaptable for use with a rotor of a centrifuge device, which rotates a cylindrical fluid, i.e. blood, tube about a rotational axis which is in substantial alignment with the longitudinal axis of the cylindrical tube while the rotor of the centrifuge device is rotating the cylindrical tube in a centrifuging direction (see Abstract and column 4). The centrifuge apparatus can, therefore, obtain optical readings of the centrifuged sample from different locations about the circumference of the fluid tube. At page 11, lines 3-13, Walters discloses that light source illuminates the transparent cylindrical tube and the detector means detects and obtains optical readings from a light reflected from the cylindrical tube, while the cylindrical tube is being rotated by the rotating means at lowered speeds of 1,000 to 2500 rpm.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have incorporated the teaching of Walters into the apparatus of Cottingham because Walters specifically taught such embodiment of an apparatus that allows a cylindrical fluid tube to rotate along its longitudinal axis while rotating the cylindrical tube in a traverse direction provides capability to obtain optical readings of the centrifuged sample from different locations about the circumference of the cylindrical tube.

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6. Claims 1, 4, 10, 13-18, 22, 26-29, 31, and 33-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940) for reasons of record.

Anderson et al. disclose a cytometric apparatus or system for characterizing microorganisms such as bacteria, virus, mycoplasma, or yeast cells in sample. The cytometric apparatus is specifically used for measuring fluorescence from the sample contained in a transparent cylinder (centrifuge tube). The apparatus comprises a rotating means (bucket) for holding and rotating the transparent cylinder, a light source such as laser, detector and optical filters for detecting light passing through or emitted from the sample (see column 10, lines 22-45). The transparent cylinder has an open end (upper region), a middle cell guide member, and a closed end (lower region) with successively smaller diameters (see columns 4-5). The open end is for receiving a sample which can be plugged with a cap and the lower end is a tubular microbanding region for isopycnic banding all the infectious particles or cells in the presence of a fluorescent dye or a combination of fluorescent dyes. Accordingly, a combination of light sources emitting at different wavelengths and detection systems can be applicable (see column 7, lines 32-41 and column 10, lines 8-21 and 46-67). Anderson et al. disclose that the inner surface of the cylinder can be modified by treatment with non-absorptive material (see column 5). The mechanical system of the apparatus and the optical signal detected from the microbanding is processed in a processing means (computer).

Anderson et al. differ from the instant invention in failing to disclose rotating the transparent cylinder along a longitudinal axis of the transparent cylinder.

Walters has been discussed supra.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have incorporated the teaching of Walters into the apparatus of Anderson et al. because Walters specifically taught such embodiment of an apparatus that allows a cylindrical fluid tube to rotate along its longitudinal axis while rotating the cylindrical tube in a traverse direction provides capability to obtain optical readings of the centrifuged sample from different locations about the circumference of the cylindrical tube.

7. Claims 19-20 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Surmodics, Inc. for reasons of record.

Cottingham, Anderson et al., and Walters differ from the instant invention in failing to disclose dibromo anthanthrone which is an organic photoreceptor material activated by a wavelength of approximately 300 nm to 100 nm.

Applicant, by way of disclosure at page 5, lines 17-22, admits that incorporation of photo cross-linking agents into the inner wall of cylinders, is known and used commercially by Surmodics, Inc. These photo-crosslinking agents include organic photoreceptor materials optimized for 300 nm - 2000 nm such as dibromo anthanthrone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the immobilized reagents in the transparent cylinders taught by Cottingham or Anderson as modified by Walters to include or otherwise substitute the photoreceptor materials, i.e. chromogenic materials and luminescent materials, with dibromo anthanthrone, because SurModics specifically taught its application and suitability on inner walls of cylinders such as those used in the devices of Cottingham, Anderson, and Walters. Further, the parameters set forth in claims 19 and 23 wherein "(the photoreceptor material) is activated by a wavelength of approximately 300 nm - 100 nm", constitute result effective variables which Surmodics, Inc. has shown may be obtained by optimization procedures. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." *Id.* at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of *Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 19 and 23 are for any particular purpose or solve any stated problem and the prior art teaches that photoreceptor materials often vary according to specific application or purpose or the sample being analyzed, the

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various detection materials and parametric requirements appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range for dibromo anthanthrone as disclosed by the prior art by normal optimization procedures.

8. Claims 2 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Saralegui et al. (US 5,439,645) for reasons of record.

Cottingham or Anderson et al. have been discussed supra. Cottingham or Anderson et al. differ from the instant invention in failing to disclose that the transparent cylinder has a bar code label. Cottingham or Anderson et al. further differ from the instant invention in failing to disclose that the rotating means comprises a stepper motor.

Saralegui et al. disclose an apparatus comprising an automatic, motor driven, and signal controlled rotating means (rotatable carousel) that holds and rotates a multiplicity of transparent polystyrene cylinders (test tube or glass or plastic) and wherein each cylinder carries a barcode label for identifying the specimen in the contained in the cylinder (column 1, line 64 to column 2, line 9). The carousel is provided with a central, vertically projecting handle and a movement means (self-centering lifter) for positioning along a vertical position (see column 3, lines 41-54 and see column 4, lines 5-18). Rotation is controlled by an electric stepper-type drive motor

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(see column 4, lines 53-55 and column 8, lines 9-11). The apparatus is also provided with a high speed barcode reader to read the coded indicia for each specimen and position sensor for identifying the position of the sample contained within the cylinder (see column 2, lines 26-31 and column). Specifically, the apparatus is provided with one or more light sources (LED, photodiodes) and detectors comprising sensing devices at fixed positions to monitor position and identification of each cylinder. Lastly, a processing means (electronic control assembly) secured to a vertical wall and a CPU controller is provided for directing automatic operations of the rotating means, the detection system, and the entire mechanical assembly (see column 3, lines 55-64 and columns 7-8).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate an electric stepper-type drive motor in the apparatus of Saralegui into the cytometer apparatus as taught by Cottingham or Anderson as modified by Saralegui, because stepper motors constitute obvious variation of rotating control means which are routinely varied in the art, as admitted by Applicant at page 9, last paragraph of Paper No. 12, and which have not been described as being critical to the practice of the invention. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the bar code labels as taught by Saralegui into the apparatus having cylindrical tubes for centrifugation as taught by Cottingham or Anderson and modified by Walters, because bar coding capability allows for accurate identification and location of specific cylindrical tubes.

Response to Arguments

9. Applicant's arguments filed 2/3/03 have been fully considered but they are not persuasive.

A) Applicant argues that the term "adapted to" is supported by the specification; thus, it is clear what is intended by the term "adapted to" if read in light of the specification.

In response, the provision of 35 USC 112, second paragraph, is for the specification to conclude with one or more claims particularly *pointing out and distinctly claiming* the subject matter which the applicant regards as his invention. Additionally, based on the specification pointed out by Applicant for support, it appears that there is no specific "modification" or "adaptation" made specifically to the recited structures, i.e. light source or detector, so as to illuminate differentially or detect differentially, from any other light source or detector. Accordingly, the rejection has been maintained.

B) Applicant argues that the functional connectivity between the calibration standards and the photoactivated linker is explicit; that they are both attached to the inner wall of the transparent cylinder and that is all that is required of an apparatus. Applicant further contends that the specification provides the functionality for both the photoactivated linker and the calibration standards.

In response, it appears that the "photoactivated crosslinker" is affixed to the inner wall of the transparent cylinder to sort cells; however, it remains unclear what comprises

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the calibration standards and how it structurally relates to the claimed apparatus so as to perform its function as a calibration standard since it does not appear to assist in sorting cells as in the photoactivated linker. Further, contrary to Applicant's contention, there is no descriptive support in the specification of any calibration standard or its structural and functional requirements, as an element in the claimed apparatus.

C) Applicant argues that the recitation of "rotating means adapted to rotate ... between 50-3000 revolutions per minute" is consistent with the disclosed invention because of the parameters used such as diameter of the transparent cylinder (1.3" inner diameter) for analyzing 20,000 eukaryotic cells per revolution given an average eukaryotic cell diameter of 5 microns, etc. Applicant contends that to obtain a cell analysis rate of 1,000,000 cells per second, 3000 rpm is needed. In as far as the lower limit, Applicant argues that it would have been obvious to one of ordinary skill, having the benefit of the disclosure that the cell may be rotated as slow as one wants but not so slow that the centrifugal force fails to keep the cells on the wall of the transparent cylinder.

In response, a provision of 35 U.S.C. 112, first paragraph is that the specification shall *contain a written description* of the invention, and of the manner and *process of making and using it, in such full, clear, concise, and exact terms* as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention, and not whether it would have been obvious to one of

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ordinary skill to have come up with the recited range based on possible parameters that are assigned to structures such as cylinder size, etc.

D) Applicant argues that Cottingham does not describe or fairly suggest the rotation of a sample along its longitudinal axis or the simultaneous rotation and interrogation of a sample via a light source. Applicant further contends that Walters which is cited in combination with Cottingham describes a centrifuge to rotate a fluid tube about its longitudinal axis but takes measurements only in increments, and only when the rotation is stopped. Applicant points to amended claims which now recite that “the light source illuminates the transparent cylinder while the transparent cylinder is being rotated” and “the detector detects optical reading from the transparent cylinder while the transparent cylinder is being rotated” and argues that that neither Cottingham nor Walters suggest the claimed invention as currently recited.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further contrary to Applicant argument that Walters takes measurement readings only at increments when the rotation is stopped, Walters, indeed, discloses that light source illuminates the transparent cylindrical tube and the detector means detects and obtains optical readings from a light reflected from the cylindrical tube, while

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the cylindrical tube is being rotated by the rotating means at lowered speeds of 1,000 to 2500 rpm at page 11, lines 3-13, just as recited in the claimed invention.

E) It is noted that the rejections of claims 1, 4, 10, 13-18, 22, 26-29, 31, and 33-34 under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), claims 19-20 and 23 under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Surmodics, Inc., and claims 2 and 21 under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Walters (US 6,135,940), as applied to claims 1, 3-4, 10-18, 22, 24-31, and 33-34 and in further view of Saralegui et al. (US 5,439,645), have not been traversed or disagreed upon by Applicant; therefore, no rebuttal has been provided therefor.

10. For reasons aforementioned, no claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday 6:00 AM to 3:30 PM and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
April 1, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641

4/4/03